ARTICLE

Evaluation of the percentage tissue altered as a risk factor for developing post-laser in situ keratomileusis ectasia

Alain Saad, MD, Perry S. Binder, MS, MD, Damien Gatinel, MD

Purpose: To assess the currently recommended percentage tissue altered (PTA) metric for its ability to screen for ectasia after laser in situ keratomileusis (LASIK).

Setting: Gavin Herbert Eye Institute, University of California, Irvine, California, USA, and Rothschild Foundation, Paris, France.

Design: Retrospective case series.

Methods: The study used a LASIK database created by 1 surgeon for LASIK cases with normal preoperative topography that had a minimum follow-up of 24 months with complete preoperative and intraoperative data to permit the calculation of PTA values to detect eyes at risk for developing ectasia.

Results: Of the eyes, 593 eyes had complete data and met the inclusion criteria. Based on measured flap thickness, 126 eyes (21%) had a PTA value of 40% or more (mean 44) and a percentage of that flap thickness accounted for the PTA (mean 66.7%; range 34% to 92%). The mean attempted laser ablation was 79.8 μm ± 29.2 (SD), and the mean residual bed thickness was 304.4 ± 29.2 μm (range 212 to 369 μm). No eye developed ectasia over a mean follow-up of 30 months.

Conclusions: The current PTA calculation when applied to a LASIK population with normal preoperative topography and flap thickness measured with ultrasound did not predict the risk for ectasia. Differences between study populations and assumptions might have accounted for the different outcomes obtained in the initially published PTA study.

J Cataract Refract Surg 2017; 43:946–951 © 2017 ASCRS and ESCRS.

Although rare, with a reported incidence between (0.04% to 0.6%),[1–4] ectasia after laser in situ keratomileusis (LASIK) remains 1 of the most devastating post-LASIK complications. Ectasia theoretically results from the loss of biomechanical integrity of the cornea, resulting in an unanticipated and progressive corneal steepening and thinning associated with increasing myopic astigmatism.[5]

Various risk factors for the development of ectasia have been identified, of which abnormal preoperative topography has been determined to be the most important.[6–15] Improved topography and risk-assessment systems have been developed to detect subclinical or forme fruste keratoconus, which if undetected, could lead to post-LASIK ectasia.[6,7,16–23] The Ectasia Risk Score System (ERSS) was developed by Randleman et al. in 2008[24] as a quantitative method of describing the risk for ectasia based on 5 criteria in a weighted manner in order of importance as follows: preoperative topography pattern, residual stromal bed (RSB) thickness, patient age at the time of surgery, preoperative corneal thickness, and treated manifest refraction spherical equivalent. The ERSS has been independently evaluated in several studies. In Chan et al.'s study,[25] topography was abnormal in 69% of cases, whereas the sensitivity of the ERSS in classifying cases at high risk was only 56%. In eyes with normal preoperative topography, Binder and Trattler[8] showed that the ERSS might not accurately predict whether patients are at increased risk for developing ectasia, and it tends to overestimate the ectasia risk in eyes with normal preoperative topography.

Preoperative corneal thickness, ablation depth, patient age, and flap thickness are thought to play roles in biomechanical change after a LASIK procedure; however, each individual factor has not been been proven to be a definitive risk factor.[8,26,27] Nevertheless, case reports[28] suggest that a risk score system can sometimes be beneficial in predicting a risk for ectasia. More recent proposals have improved on previous risk score systems.[29]

Submitted: January 5, 2017 | Final revision submitted: April 12, 2017 | Accepted: April 28, 2017

From the Rothschild Foundation (Saad, Gatinel) and the Center of Expertise and Research in Optics for Clinicians (Saad, Gatinel), Paris, France; American University of Beirut (Saad), Beirut, Lebanon; Gavin Herbert Eye Institute (Binder), Department of Ophthalmology, University of California Irvine, Irvine, California, USA.

Corresponding author: Alain Saad, MD, American University of Beirut, PO Box 11-0236, Beirut, Lebanon. E-mail: dralainsaad@gmail.com.

0886-3350/$ - see frontmatter
http://dx.doi.org/10.1016/j.jcrs.2017.04.040

The concept of percentage tissue altered (PTA) as a calculated ectasia risk factor was introduced by Santhiago et al.[30–32] The PTA represents the percentage of central corneal tissue modified during the creation of the LASIK flap and subsequent stromal photoablation. It considers the relationship between the preoperative corneal thickness, tissue altered (ablated) through excimer laser ablation and flap creation, and the ultimate RSB thickness. It has been recommended as a screening metric for refractive surgery candidates. In Santhiago et al.'s study[30] of eyes with suspicious preoperative topography, the PTA had a higher discriminative capability than the RSB thickness for post-LASIK ectasia. To our knowledge, at present no published studies have independently validated the PTA concept.

Our study evaluated the values of the PTA metric by computing its value in well-documented cases of LASIK in which intraoperative pachymetry was performed in all eyes to measure the central flap thickness.

PATIENTS AND METHODS

The analysis was performed using a database program, Outcomes Analysis Software (version 5.2, Accelerated Vision, Inc.), which was designed for the ophthalmology field. This is the same software used for previous analyses of ectasia risk.[8] All procedures were performed by the same surgeon (P.S.B.). The primary source of data entry was the surgeon.

The database was queried to look for LASIK cases with a minimum follow-up of 24 months that had complete data, including the mechanism of flap creation and intraoperative ultrasound (US) pachymetry measurement of created flap thicknesses, as well as the recorded attempted excimer laser ablation depth. The cases were entered into the database between 1997 and 2008. The database did not save the topographies and the following topographers were used: Eyesys (Eyesys Vision, Inc.), C-scan (Technomed GmbH), Humphrey Atlas (Carl Zeiss Meditec AG), Pentacam (Oculus Optikgeräte GmbH), and Allegretto Wavelight Topolyzer (Alcon Laboratories, Inc.). As previously reported,[33] subtraction US flap thicknesses were measured by the surgeon using 2 different US pachymeters. The selected cases were exported into Excel software (Office v39, Microsoft Corp.). All cases had a standard preoperative refractive surgery screening that included corneal topography.[8]

Analysis columns were created to calculate the PTA according to the following formula recommended by Santhiago et al.[30–32]:

$$\text{PTA} = [(\text{flap thickness} + \text{excimer laser ablation}) / \text{preoperative CCT}] \times 100$$

which allows the expression in whole numbers and where CCT is the central corneal thickness. Preoperative flap thickness was determined using central US pachymetry performed by the surgeon on the center of the entrance pupil immediately before flap creation and immediately after the created flap was reflected. There were no fluids used to assist in the measurement.

The attempted excimer laser ablation was recorded directly from the individual excimer laser to the database. A study by Flanagan and Binder[34] confirmed that the attempted laser ablation closely represents the actual central laser ablation. The PTA was calculated based on actual measured flap thickness and on attempted flap thickness. The percentage of the PTA value that was produced by each flap thickness measurement was also calculated after discarding 2 eyes with erroneously measured flaps thinner than 50 μm.[35] The eyes selected had PTA values of 40% or more as recommended by Santhiago et al.[30–32] Comparisons of groups of paired eyes were performed using the Student *t* test. A topographic examination was performed at each postoperative visit to rule out ectasia and suspicious topographic changes.

RESULTS

The study comprised 593 eyes with a minimum follow-up of 24 months (mean 30 months; range 24 to 108 months) that had normal preoperative topography and preoperative CCT and intraoperative flap thickness measurements (Table 1). Of these, 126 eyes had a PTA value of 40% or more (based on measured flap thickness) (mean 44%; range 40 to 64%).

Five hundred twenty-nine (89%) LASIK flaps were created with a mechanical microkeratome (314 with the Chiron Automated Corneal Shaper, 210 with the Summit-Krumeich-Barraquer microkeratome, 4 with the Phoenix Keratec, 1 with the Medlogics microkeratome) and 64 with the

Table 1. Characteristics of the study population.

Parameter	Total Cohort (593 Eyes; 47% Men)	PTA ≥40% (Flap Measured) (126 Eyes; 38% Men)		PTA <40% (Flap Measured) (467 Eyes; 50% Men)	
	Mean ± SD	Mean ± SD	Range	Mean ± SD	Range
Age (y)	42.0 ± 10.2	40.6 ± 9.5	21, 59	42.23 ± 10.3	20, 74
Attempted correction SE (D)	−5.1 ± 3.1	−7.0 ± 3.8	−18, −0.4	−4.6 ± 2.6	−13.5, −0.4
Flat K (D)	43.9 ± 1.6	44.2 ± 1.4	39.4, 48.5	43.9 ± 1.6	39.2, 48.2
Steep K (D)	45.0 ± 1.6	45.5 ± 1.3	42.1, 48.5	44.9 ± 1.6	41.0, 49.7
Planned flap thickness (μm)	161.6 ± 30.9	169.2 ± 27.2	90, 240	159.6 ± 31.6	90, 240
US preop CCT (μm)	547 ± 37	543 ± 35	435, 627	548 ± 37	429, 664
US measured central flap thickness (μm)	133 ± 30	158.7 ± 27.0	91, 246	126.3 ± 27.3	17, 230
Planned laser ablation (μm)	58.7 ± 26.5	79.8 ± 29.2	18, 223	52.7 ± 22.2	7, 116
US RSB thickness (μm)	358 ± 46	304.4 ± 29.2	212, 369	372.5 ± 38.3	271, 540
Attempted measured flap thickness (μm)	28 ± 44	9.0 ± 44	—	33.6 ± 42.1	—
PTA (flap measured) (%)	34.6 ± 6.8	43.9 ± 3.7	40, 64	32.1 ± 4.9	14, 39.9
PTA (flap attempted) (%)	40.0 ± 8.5	45.8 ± 9.3	34, 78.8	38.4 ± 7.5	15, 67.7
Flap thickness portion (%) of total PTA	69.8 ± 11.4	66.7 ± 10.2	34, 92	70.5 ± 11.8	24, 95
Flap stromal portion (%) of total PTA	43.3 ± 12.6	45.5 ± 10.1	19, 69	42.7 ± 13.1*	1.5, 74.6

CCT = central corneal thickness; K = keratometry; PTA = percentage tissue altered; RSB = residual stromal bed; SE = spherical equivalent; US = ultrasound

*After discarding 2 eyes with erroneously measured flaps <50 μm